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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,358	PARKER, DAVID	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/28/06; 4/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Applicant's preliminary amendment filed April 28, 2006 is acknowledged and has been entered. Claims 1-39 have been cancelled. Claims 40-87 have been added. Accordingly, claims 40-87 are pending and are under examination.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The disclosure is objected to because of the following informalities: A Brief Description of the Drawings is missing.

Appropriate correction is required.

Information Disclosure Statement

5. The information disclosure statement filed April 16, 2007 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. Reference number 27 has not been considered because the author of the reference has not been listed both in the document and in Form 1449.

The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is vague and indefinite in reciting, “wherein said plasma and lymphocyte antibodies are detected together” because it is unclear how lymphocyte antibodies which are intracellular components of lymphocytes can be detected together, i.e. at the same time, with the plasma antibodies. See also claim 51.

Claim 42 is ambiguous in reciting, “further comprising the steps of (i)…; and (ii)…" because it is unclear how the method steps interrelate functionally with the method steps recited in claim 40. It is specifically unclear when the isolation steps in (i) and (ii) are performed in relation to the method steps in claim 40.

Claim 43 is ambiguous in reciting, “further comprising the steps of (i)…; and (ii)…" because it is unclear how the method steps interrelate functionally with the method steps recited in claims 40 and 41 from which it depends. It is specifically unclear when the isolation steps in (i) and (ii) are performed in relation to the method steps in claims 40 and 41.

Claim 44 is indefinite in reciting, “a lymphocyte containing sample and a plasma containing sample” because it is unclear what other component is contained in the “sample.” Does Applicant simply intend, “lymphocyte sample” and “plasma sample?” See also claims 45, 46, 47, 48, 49, 50, and 77.

Regarding claim 47, the phrase "said plasma …sample or said lymphocyte … sample are recombined" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or … are recombined"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). It is specifically unclear what the plasma sample and the lymphocyte sample are being recombined with.

Regarding claim 48, the phrase "said plasma …sample or said lymphocyte … sample are recombined" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or … are recombined"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). It is specifically unclear what the plasma sample and the lymphocyte sample are being recombined with.

Claim 62 is vague and indefinite in reciting, “wherein the chemical disruption buffers contain detergent” because it is unclear what other component is contained in the “chemical disruption buffers.” Does Applicant simply intend, “the chemical disruption buffer is a detergent?”

Claim 78 is indefinite in reciting, “DMSO.” Acronyms or abbreviations should be defined at least one time in a given set of claims.

Claim 87 is vague and indefinite in reciting, "appropriate" because the term "appropriate" is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 40-48, 52-77, 79-84, and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Haaheim (US Patent 7,361,479).

Haaheim discloses a method of determining the presence and amount of antibodies to immunogen in a whole or peripheral blood sample (Abstract; col. 3, lines 29-38, 39-49; col. 4, lines 39-45; col. 5, lines 3-9; col. 8, lines 44-54; col. 9, lines 27-31). In practice, Haaheim teaches isolating or purifying lymphocytes from a blood sample

and then contacting the isolated/purified lymphocytes with a lysis reagent or detergent (disruption buffers or physical disruption) to lyse or disrupt the lymphocytes so as to release antibodies to immunogen (col. 3, lines 7-10; col. 4, lines 52-55; line 64 to col. 5, line 2; col. 9, lines 14-27; col. 10, lines 1-22). Haaheim also teaches separating plasma from the whole blood sample. The whole blood sample is divided into portions so as to prepare and purify an isolated lymphocyte sample and a separated plasma sample (col. 9, lines 14-25, 54-58). Thereafter, detection antibodies or antigens that recognize and bind the released antibodies to the immunogen, and that are immobilized to solid phase are contacted with the lysed lymphocyte sample so as to allow binding of the immunogen antibodies released from the lymphocytes to the detection antibodies or antigens and detection of the immunogen antibodies in a solid phase immunoassay such as ELISA and produce a spectrophotometric signal (col. 5, lines 31-47; col. 10, lines 30-54). Detection antibodies or antigens that recognize and bind antibodies to the immunogen and that are immobilized to solid phase are also contacted with the isolated plasma sample so as to allow binding of the immunogen antibodies in plasma to the detection antibodies or antigens and detection of the immunogen antibodies in a separate solid phase immunoassay such as ELISA by production of a spectrophotometric signal (col. 6, lines 8-16; col. 11, lines 5-38; col. 12, lines 41-67). Haaheim specifically teaches that information obtained from the assay result can be supplemented by using data on pre-existing plasma antibodies obtained from the classical ELISA test. Additionally, after separation of lymphocytes from the blood sample, the remaining plasma fluid may be used for detecting pre-existing antibodies

using the same binding components and solid phase as taught used for detecting the released antibodies from the lysed lymphocytes (col. 13, lines 15-23). Haaheim teaches that the blood sample is from a human or mammalian source and can be assayed at a volume of 1 ml. (col. 7, line 64 to col. 8, line 23). Haaheim also teaches using a negative control or reference control to diagnose or monitor infection of a human or animal by the immunogen and the extent of infection by reference to standard control (col. 4, lines 2-12; col. 5, lines 13-17; col. 6, lines 17-22). The blood sample or the lymphocyte portion is stored at 4C or less (freezing or less than zero) before the lymphocytes are lysed (col. 3, lines 11-23; col. 6, line 59 to col. 7, line 23). The lymphocytes in the sample are not incubated under conditions that allow production or secretion of antibodies prior to the method (col. 6, lines 45-46, 48-59; col. 7, lines 18-23; col. 8, lines 57-62;). Haaheim further teaches assaying multiple samples simultaneously or sequentially in a high-throughput screening method (col. 7, lines 38-59). The immunogen in the method of Haaheim results from infection or vaccination and may be either a bacterial antigen or a viral antigen. The infection of the animal by the immunogen occurs less than 10 days (within a few days; 8-12 days; 1-5 days; 2-3 days) before the blood sample is obtained or collected (col. 4, lines 13-43). The immunogen may be any one of Herpes Simplex Virus, Cytomegalovirus (CMV), human immunodeficiency virus (HIV), Hepatitis, or Epstein-Barr (EBV). The method as taught by Haaheim identifies an animal or human infected with the immunogen such as an HIV patient (col. 8, lines 24-31).

In as far as claims 47 and 48, since the element upon which the plasma sample or the lymphocyte sample is not clearly defined, and that the plasma sample and the lymphocyte sample as taught by Haaheim are combined and mixed with elements such as reagents and antibodies, it is deemed that the teaching of Haaheim reads on the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaheim (US Patent 7,361,479).

Haaheim has been discussed supra. Haaheim differs from the instant invention in failing to teach that the ratio between the plasma sample and the lymphocyte sample is 1:0.04 to about 1:4. Haaheim also does not teach that both the plasma antibodies and the lymphocyte antibodies are [both] detected in a single assay.

However, combining the samples containing plasma antibodies and lysed lymphocyte antibodies into a single sample would appear to be obvious in view of the explicit teaching of Haaheim of the additional use of plasma samples for obtaining further information on antibodies present in the whole blood sample. One of ordinary skill in the art at the time of the instant invention would have been motivated to combine

the plasma sample and the lysed lymphocyte sample so as to obtain a cumulative quantitation of the immunogenic antibodies present in the whole blood sample because it provides for simplification of the antibody assay system.

In as far as the recitation of plasma sample to lymphocyte sample ratio recited in claims 49 and 50, it is maintained that the ratio of samples used in an assay to obtain required analyte result all encompass result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 49 and 50 are for any particular purpose or solve any stated problem, and other selected solutions and parameters appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

10. Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaheim (US Patent 7,361,479) in view of Lionetti et al. (US Patent 4,004,975).

Haaheim has been discussed supra. Haaheim differs from the instant invention in failing to teach freezing the whole blood sample with from about 5% to about 15% DMSO before lysing the lymphocytes.

Lionetti et al. teach freezing buffy coat from a whole blood sample in the presence of 5% to 10% DMSO (dimethyl sulfoxide) which is used as a cryoprotective agent so as to protect the integrity of white blood cells including lymphocytes and preserve them. According to Lionetti et al., DMSO has been used extensively as an intracellular cryoprotective agent of nucleated cells due to its high rate and universality of its cellular penetration (Abstract; col. 1, lines 44-48; col. 11, lines 33-46).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to store the whole blood sample as taught by Haaheim with 5% to 15% DMSO as taught by Lionetti because Lionetti taught that DMSO is well-known and conventionally used as intracellular cryoprotective agent in storing nucleated cells because of its advantage of high rate and universality in cellular penetration.

11. Claims 85 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaheim (US Patent 7,361,479) in view of Busch et al. (Chapter 2: Closing the Windows on Viral Transmission by Blood Transfusion, Blood Safety in the New Millenium, Stramer SL Ed, AAB: 33-54 (2001)).

Haaheim has been discussed supra. Haaheim differs from the instant invention in failing to teach that the assay screening is for blood bank samples and transplantation or transfusion samples.

Busch et al. teach using HIV and other viral antibody detection methods for screening blood bank samples for determining transfusion or transplant suitability (p. 36, last full paragraph to p. 37).

One of ordinary skill in the art at the time of the instant invention would have been motivated to use the antibody detection method as taught by Haaheim for application with blood bank, transfusion, and transplant samples as taught by Busch because Haaheim taught that his method provides a simple, quick, yet reliable method to accurately quantify antibody production in response to infection and vaccination and Busch specifically recognized and suggested that quantitative data and accurate models are needed in projecting and preventing infectious donations such as in the case of HIV.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

September 17, 2009